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AdvaMed

Advanced Medical Technology Association

November 27, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1367; Postmarket Surveillance; Proposed Rule

Dear Sir or Madam:

These comments are submitted by the Advanced Medical Technology Association (AdvaMed) in response to the Food and Drug Administration's (FDA) proposed rule to implement the postmarket surveillance (PS) provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act), as amended by the FDA Modernization Act of 1997 (FDAMA). See 65 Fed. Reg. 52,376 (Aug. 29, 2000). AdvaMed is a Washington, D.C.-based trade association and the largest medical technology association in the world. AdvaMed represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's members manufacture nearly 90 percent of the \$68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the \$159 billion purchased annually around the world.

I. General Comments

As a general matter, AdvaMed is concerned that, if implemented in its current form, FDA's PS proposed rule would impose substantial, unnecessary burdens on device manufacturers. Pursuant to the FDC Act, the objective of PS is "the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health." 21 U.S.C. § 360(l). In AdvaMed's view, this objective could be achieved without many of the burdens imposed by the proposed rule.

AdvaMed is further concerned that FDA's proposal would be especially onerous for small device manufacturers. As the agency acknowledges, the companies that would be affected by the requirements of the proposed rule are "typically small" -- on average \$9.8 million in annual revenues and 72 employees. 65 Fed. Reg. 52,384-5. If implemented in its current form, the proposed rule is likely to have a "chilling" effect, driving some small

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companies out of business, and creating a barrier to entry for others. Such attrition ultimately will have a negative impact on public health, as these small device manufacturers often are the innovators of important new medical technologies.

In the section-by-section analysis below, AdvaMed describes how device manufacturers -- and, particularly, small device manufacturers -- would be affected by the requirements of the proposed rule. AdvaMed believes that the unnecessary burdens imposed by the proposal result, in part, from an unrealistic conception of PS. Indeed, in certain respects, the proposed rule appears aimed at stimulating the collection of "interesting data" -- rather than data useful to protecting patients. In AdvaMed's view, the burdens imposed by the proposed rule are further amplified by a lack of clarity and certainty in some sections. Therefore, in the discussion below, AdvaMed provides specific recommendations as to how the PS proposed rule could be modified and clarified to lessen the burden on device manufacturers, without diminishing its capacity to facilitate the collection of data that is necessary to protect public health.

II. Section-by-Section Analysis

A. "Organization and Format" Section, 65 Fed. Reg. 53,378

1. The "Plain Language" Used in the Proposed Rule Made it Clear and Easy to Read.

In describing the organization and format of the proposed rule, FDA states:

We have tried to make each section of the proposed rule easy to understand by using clear and simple language rather than jargon, keeping the sentences short, and using active voice rather than passive voice whenever possible. We would like your comments on how effectively we have used plain language, the organization and format of the proposed rule, and whether these have made the document clear and easy to read.

65 Fed. Reg. 52,378. AdvaMed found the proposed rule very readable, and commends FDA on its effective use of "plain language" and logical formatting. The "question and answer" style was clear and easy to follow, and AdvaMed encourages the agency to use this approach in future rulemakings.

B. "General" Section, 65 Fed. Reg. 52,378

1. FDA Should Provide Guidance as to When Manufacturers Will Be Required to Conduct PS in Support of a New Indication for Use.

In describing the objective of the proposed rule, FDA states:

The proposed regulation is intended to ensure that useful data or other information will be collected to address public health issues or questions related to the safety and effectiveness of devices for which the agency has issued PS orders. These issues or questions may include, among other things . . . the rate of known adverse events as the indications for use of the device change

65 Fed. Reg. 52,378 (emphasis added).

Based on the above statement, AdvaMed is concerned that, through PS submissions, FDA intends to increase the amount of data required to support a new indication for use. Indeed, under current agency policy, firms wishing to modify the indications of use for an existing device already are required in many instances to submit a new premarket notification (510(k)) or a premarket approval application (PMA) supplement. See "Deciding When to Submit a 510(k) for a Change to an Existing Device," 510(k) Memorandum #K97-1 (Jan. 10, 1997); 21 C.F.R. § 807.81(a)(3); 21 C.F.R. § 814.39(a)(1). Faced with the burden of making another submission, after a new 510(k) clearance or PMA supplement approval, some firms would decide against seeking clearance/approval of a new indication for use. Thus, AdvaMed respectfully requests that FDA establish guidance outlining the circumstances under which manufacturers would be required to conduct PS in support of a new indication for use.

C. "Notification" Section, 65 Fed. Reg. 52,379

1. PS Orders Should Contain FDA's Justification for Selecting PS Over Other, Less Burdensome Alternatives.

FDA states that it will notify manufacturers that PS is required by sending them a "postmarket surveillance order," which will specify "the device(s) subject to the surveillance order, the reason that we are requiring PS, and any general or specific guidance that is available." 65 Fed. Reg. 52,379. In AdvaMed's view, the PS order also should contain the agency's justification for requiring PS, as opposed to other, less burdensome alternatives, such as reliance on medical device reporting (MDR) reports.

For device manufacturers -- and especially for small manufacturers -- conducting PS potentially presents a significant economic burden. Thus, before ordering PS, it is important that the agency assess all other possible alternatives. Significantly, FDA's PS guidance document instructs agency review staff that "[c]onsideration should be given to whether other mechanisms may address the [surveillance] question, such as postapproval requirements, MDR, quality system requirements, field inspections, or special controls." See "Guidance for

Industry, Review Staff, and the Clinical Community: Guidance on Criteria and Approaches for Postmarket Surveillance" (Nov. 2, 1998) at 2.¹ By including in the postmarket surveillance order its justification for selecting PS over other alternatives, FDA will provide affected firms with a fuller understanding of the agency's concerns. This information is especially important for companies who may disagree with FDA's decision to order PS.

2. FDA Should be Required to Meet with Manufacturers Prior to Issuing a PS Order.

In the "Notification" section, FDA states that

a manufacturer may have difficulty designing and submitting a PS plan to FDA within the statutory time frame of 30 days from receipt of a surveillance order. We may, therefore, request a meeting with the affected manufacturer(s) to discuss the surveillance question and the possible approaches for the surveillance. We anticipate that this would generally occur prior to issuing a surveillance order for a particular device for the first time, and would be less likely to occur for subsequent orders for the same or similar devices. We may also request information from or meetings with manufacturers to determine whether a surveillance order is appropriate or necessary.

65 Fed. Reg. 52,379.

In AdvaMed's view, 30 days rarely will be adequate to prepare a proper PS plan. As such, AdvaMed believes it is critical that FDA and the affected manufacturer(s) meet before the PS order is issued, to discuss whether PS is necessary, or whether the agency's concerns could be adequately addressed through other, less burdensome mechanisms. If FDA and the manufacturer(s) agree that PS is appropriate, the meeting would serve as a forum to discuss the nature of the PS question and what the agency expects to see in a PS plan. Such a discussion would assist the affected manufacturer(s) in preparing and submitting a suitable plan within the 30-day time limit. Therefore, AdvaMed respectfully requests that FDA modify the proposed rule to require the agency to meet with the affected manufacturer(s), prior to issuance of a PS order.

¹ In considering alternatives to PS, AdvaMed urges the agency to consider the current performance of such alternative mechanisms, rather than discarding them based on historical problems. For instance, in the "Legislative History" section of the preamble to the proposed rule, the agency notes various weaknesses in the MDR reporting system, e.g., a General Accounting Office (GAO) report found that "only 50 percent of class I recalls, the recall classification associated with device-related serious adverse health consequences or death, were preceded by MDR's." 65 Fed. Reg. 52,377. However, the GAO report in question was published in 1989, and may not reflect the current performance of the MDR system.

3. A Mechanism Should be Established for Alerting Manufacturers Regarding Which Devices May be Affected by PS.

AdvaMed urges FDA to modify the proposed rule or issue guidance to provide a mechanism for putting device manufacturers on notice as to what sort of devices may be subject to PS. For device manufacturers contemplating marketing a particular type of device, it is important to understand whether that device is likely to be the subject of a PS order. Indeed, some manufacturers -- particularly small manufacturers -- may choose not to enter a particular market because of the economic burdens associated with conducting PS.

In order to ensure the broadest possible notification, AdvaMed recommends that FDA post on its website a list of the generic types of devices that will be, and that may be, subject to PS. In addition, AdvaMed respectfully requests that FDA establish a mechanism within the agency's Office of Device Evaluation to alert manufacturers during the review process that PS may be required. This would help reduce the uncertainty for manufacturers who are trying to decide whether to market a particular device.

D. "Postmarket Surveillance Plan" Section, 65 Fed. Reg. 52,379

1. Domestic Manufacturers of Devices for Export Only Should Not be Subject to PS Requirements.

In delineating the scope of the proposed rule, FDA states that "[d]omestic manufacturers marketing a device for export only are also subject to the [PS] provisions of section 522(a) of the act because they are introducing the device into interstate commerce under the terms of the act." 65 Fed. Reg. 52,379. In AdvaMed's view, subjecting domestic manufacturers of devices for export only to PS requirements is inconsistent with both the purpose of PS and the intent of FDA's export provisions.

The clear objective of PS is to gather additional information on devices that have gone through FDA's premarket review process, and have been cleared or approved for marketing. Indeed, in drafting the FDC Act's PS provisions, Congress observed:

[P]remarket approval cannot detect all possible problems which may occur after a device is marketed. The Committee, therefore, expects that implants and other devices critical to human health will be subject to postmarket surveillance for some appropriate period of time after they are first marketed.

H. Rept. 808, 101st Cong., 2d sess., p. 32, 1990, quoted at 65 Fed. Reg. 52, 378.

In contrast, the FDC Act's export provisions permit, among other things, the export of certain unapproved devices, *i.e.*, products that cannot be lawfully marketed in the U.S. because they have received no premarket scrutiny. See 21 U.S.C. §§ 381 & 382. To subject such products to PS is illogical, given that the function of PS is to generate additional data, above and beyond that which was evaluated during the premarket review process.

Furthermore, conducting PS studies on devices for export only does not benefit public health in the United States, because the devices in question are not sold in the United States. Rather, this is a matter more appropriately addressed by the regulatory processes of the foreign countries importing these devices. Thus, AdvaMed respectfully requests that FDA modify the proposed rule to specifically exclude manufacturers of devices for export only from the scope of PS requirements.

2. A "Two-Tier" Approach to PS Would be More Likely to Generate Useful Data.

In describing the contents of a "postmarket surveillance plan," FDA states: "It is essential that the manufacturer design the plan to address the specific PS question we have identified in the order." 65 Fed. Reg. 52,379. AdvaMed believes that this statement reflects a potentially inefficient approach to PS, which, if implemented, could result in FDA conducting a search for "interesting data." In AdvaMed's view, such an approach could impose a significant burden on manufacturers, and, in certain situations, would be unlikely to yield information useful to protecting patients.

The fact is that, in some cases, it will be unrealistic for FDA to identify a "specific question" in a PS order -- because the specific question will not be known. Rather, AdvaMed believes that a better approach to PS would be to utilize a "two-tier" system. Under such a system, the "first tier" would involve the manufacturer(s) collecting information regarding significant complications. This could be done through education of the appropriate staff at selected centers and through the use of clinical report forms. If the results of the "first tier" yielded a "specific question," *i.e.*, evidence of unexpected serious illnesses, injuries, or deaths due to the use of the device, then, as the "second tier," a broader, more in-depth information collection effort could be utilized to address the specific question. In contrast, if no "specific question" were identified, then the postmarket surveillance would be considered complete.

In sum, the "two-tier" system would utilize a deliberative, science-based approach to identifying a specific question for study. In AdvaMed's view, such an approach would be much more likely to generate data useful to protecting patients than a system under which manufacturers are simply directed to study a question -- without a "first tier" inquiry to determine if that question merits study. As such, AdvaMed respectfully requests FDA to modify the proposed rule to incorporate a "two-tier" approach to PS.

3. FDA's Informed Consent and IRB Requirements Should be Largely Inapplicable to PS Studies.

In describing the requirements applicable to PS studies, FDA states:

In general, the regulations governing protection of human subjects (21 C.F.R. Part 50) and institutional review boards (IRB's) (21 C.F.R. Part 56) apply to studies of unapproved and approved products regulated by FDA. This may include PS studies, depending on the approach used. There are some approaches to PS, such as the review of published literature, where the informed consent and IRB regulations would not be applicable. For other types of studies, for example, prospective studies, the patient should be provided with the basic elements of informed consent, including the extent to which records would be kept confidential. Therefore, a manufacturer should consider the need for IRB approval and informed consent when designing a surveillance plan. . . .

We invite comments on the issue of informed consent for PS.

65 Fed. Reg. 52,379-80 (emphasis added).

AdvaMed believes that, with the exception of a very limited consent involving confidentiality of patient records, FDA's informed consent regulations (21 C.F.R. Part 50) and IRB requirements (21 C.F.R. Part 56) should be largely inapplicable to PS studies. Indeed, with respect to medical devices, the scope of Parts 50 and 56 is specifically limited to investigational device exemption (IDE) studies and studies to support "applications for research or marketing permits." See 21 C.F.R. §§ 50.1 & 56.101. FDA's regulations define "application for research or marketing permits" to include several types of data submissions. 21 C.F.R. § 50.3(b). However, postmarket surveillance reports are not included in this definition, thus indicating that the requirements in Parts 50 and 56 do not apply to PS studies.²

4. FDA Should Clarify What it Means to Include Device "Claims" in a PS Submission.

In Proposed § 822.9, FDA states that a manufacturer ordered to conduct PS must make a submission to the agency containing, among other things "indications for use and claims for the device." Proposed § 822.9(a)(8) (emphasis added). AdvaMed respectfully requests clarification regarding the term "claims." For example, does the agency expect manufacturers

² The FDC Act's PS provisions were incorporated into the Act in 1990. See 65 Fed. Reg. 52,377. In AdvaMed' view, had FDA intended its informed consent and IRB requirements to apply to PS studies, at some point over the last 10 years, the agency would have amended the definition of "application for research or marketing permit" to include PS reports.

to submit all of the labeling and promotional materials for the device in question? If so, AdvaMed respectfully requests that FDA explain why such an extensive submission regarding device "claims" is needed, and how it would relate to the agency's evaluation of a manufacturer's PS plan.

E. "FDA Review and Action" Section, 65 Fed. Reg. 52,380

1. FDA Should Define its Criteria for Evaluating PS Plans.

The proposed rule contains only general statements regarding the criteria FDA will apply in assessing PS plans. For example, in the preamble, FDA states: "We will evaluate the plan for scientific soundness, feasibility, and appropriateness to address the surveillance question." 65 Fed. Reg. 52,380 (emphasis added). Likewise, Proposed § 822.16 states that the agency will consider "whether the surveillance plan will result in the collection of useful data that will answer the surveillance question."

In order to prepare an appropriate PS plan, manufacturers need to understand the specific criteria FDA will apply in assessing the plan. Therefore, AdvaMed respectfully requests that FDA modify the proposed rule or issue guidance to clarify the specific factors it will consider in deciding whether to approve a plan. In particular, AdvaMed asks that FDA define broad terms such as "scientific soundness."

2. Manufacturers Should be Required to Obtain Approval Only for Significant Changes in PS Plans.

FDA states that "[a]ny proposed modifications or changes in an ongoing study by the manufacturer must be submitted in writing for FDA approval prior to execution." 65 Fed. Reg. 52,380. In AdvaMed's view, this is an unnecessary and overly burdensome requirement. Indeed, AdvaMed can identify no benefit to the patient from requiring manufacturers to seek FDA approval for "any proposed modification" to a PS study. Rather, in AdvaMed's judgment, the more appropriate approach would be to require agency approval of "significant" changes, i.e., changes that would affect the nature of data collected pursuant to the PS plan.

As an important point of comparison, sponsors of investigational device exemption (IDE) studies are not required to obtain prior agency approval before making "any" change to a clinical protocol. Rather, a modification may be made without FDA approval, provided that the sponsor notifies FDA of the modification, and provided that the modification does not affect:

- The validity of the data or information resulting from completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon

to approve the protocol;

- The scientific soundness of the investigational plan; or
- The rights, safety, or welfare of the human subjects involved in the investigation.

21 C.F.R. § 812.35(a)(3). AdvaMed believes that a similar approach should be implemented for PS, and respectfully requests that FDA modify the proposed rule to require that manufacturers obtain FDA approval only for significant changes in a PS study.

3. PS Plans Should Remain Confidential At Least Until the Final PS Report is Submitted.

With respect to the confidentiality of PS plans, FDA states:

Until the plan is approved, FDA considers the contents of the submission confidential. Once we approve the plan, the contents of the original submission, amendments, supplements, and reports are disclosable in accordance with the Freedom of Information Act. We will continue to protect the confidentiality of trade secret or commercial confidential information, and information identifying individual patients.

65 Fed. Reg. 52,380.

In AdvaMed's view, approval of a PS plan should not be the point at which the contents of the plan becomes disclosable under the Freedom of Information (FOI) Act. Rather, AdvaMed believes that, at most, disclosure at this point should be limited to the fact that an order to conduct PS has been issued. In AdvaMed's judgment, the contents of PS plans should remain confidential at least until the manufacturer's final PS report is submitted, as earlier disclosure could provide the manufacturer's competitors with insight into commercially sensitive issues. AdvaMed respectfully requests that FDA modify the proposed rule in this regard.

F. "Records and Reports" Section, 65 Fed. Reg. 52,381

1. Inspections to Review PS Programs Should be Subject to FDA's "Preannounced Inspections Policy."

With regard to inspections of facilities conducting PS studies, FDA states:

We will review manufacturers' PS programs during inspections. In addition, persons with PS obligations other than manufacturers, e.g., clinical investigators, will be subject to periodic inspections. Any person authorized to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any facilities where devices are held (including any establishment where devices are packed, held, used, or implanted, or where records of results from the use of devices are kept).

65 Fed. Reg. 52,381. AdvaMed believes that inspections to review postmarket surveillance programs should be subject to FDA's "Preannounced Inspections Policy," under which firms typically are contacted at least five days in advance of an inspection. See 61 Fed. Reg. 14,787 (April 3, 1996). AdvaMed respectfully requests that FDA modify its Preannounced Inspections Policy to specifically include inspections of PS programs. See Id.

G. "Economic Impact" Section, 65 Fed. Reg. 52,382

1. FDA's Notion of the Design and Objective of PS Studies Reflects an Unrealistic Conception of PS.

In describing the design of PS studies, FDA states:

The surveillance becomes larger and more extensive as the acceptable rate of adverse events becomes smaller. . . . For example, the surveillance must include about 30,000 observations to be 95% confident that a PS will detect events that occur at a frequency of 0.0001 (1 event out of 10,000 observations). The PS designed to detect more frequent events requires fewer observations.

65 Fed. Reg. 52,382 (emphasis added). In AdvaMed's view, the idea that manufacturers would conduct PS studies involving 30,000 observations reflects an unrealistic conception of PS, and reinforces AdvaMed's concern that the proposed rule may, in certain respects, be aimed at stimulating the collection of "interesting data," rather than data useful to protecting patients.

FDA states that 30,000 observations are needed to detect events that occur at a rate of 1 in 10,000. However, the reality is that most manufacturers -- particularly small manufacturers -- do not even sell enough devices to collect 30,000 observations. In AdvaMed's view, this demonstrates that, as a general matter, PS studies should not be used to capture event rates as low as 1 in 10,000. Indeed, AdvaMed believes that, unless there is evidence of a significant public safety problem, and there exists adequate justification for using PS to address such problem, the objective of PS generally should not be to detect extremely low-occurrence, random events, i.e., "interesting data." Rather, what is more useful for protecting patients --

and more realistic for manufacturers -- is to utilize PS studies to better define true rates of expected occurrences.

2. FDA Does Not Have the Authority to Authorize Clinical Studies Under PS.

In assessing the costs involved in conducting PS, FDA states that, "[f]or purposes of this analysis, we estimate that 10 percent of the PS will require primary data collection [collected from clinical trials], 50 percent may utilize secondary data sources, and 40 percent may collect adequate data from published reports." 65 Fed. Reg. 52,382. AdvaMed believes that, based on the legislative history of Section 522, the FDA is not authorized to require clinical studies for PS.

The original requirement for PS came from Section 522 of the Safe Medical Devices Act of 1990, which for the first time required a device manufacturer to conduct PS and submit a protocol for FDA's approval. The FDA was to determine if the "investigator" identified in the protocol was appropriate and whether "the protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device." Section 522(b). The legislative history used the term "monitoring" to describe what postmarket surveillance was supposed to be. The Senate Report stated that "[t]he Committee intends this section to allow for clinical monitoring of the earliest experiences with a device." S. Rep. No. 101-513, 2d Sess. at 29 (1990). The Conference Report uses the monitoring language as well. Monitoring clinical experience in the FDA context is very different from undertaking a clinical study. Nevertheless, in implementing postmarket surveillance, FDA interpreted the statute as giving it the power to require prospective clinical studies. In 1991, HIMA (now AdvaMed) disagreed with that view.

In 1997, Congress was more explicit in stating its intent. In the statute and legislative history, Congress communicated that postmarket surveillance did not include prospective clinical trials. In the statute it replaced the word "protocol" with the word "plan" and the term "investigator" with the term "person" and charged the agency with determining "if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health." Section 522(b). Also, the "safety and effectiveness" language from the "Safe Medical Devices Act of 1990" was deleted, thus, further evidencing Congress' intent to make clear that postmarket surveillance was not intended to prove safety and effectiveness. In order that there be no misunderstanding about these word changes, the Senate in its committee report accompanying this language, stated that "[t]he committee is concerned that FDA not interpret the postmarket surveillance authority as power to require longitudinal studies for FDA approved products." S. Rep. No. 105-43, 1st Sess. at 37 (1997). Clearly, postmarket surveillance may not include clinical studies.

3. FDA Should Define the Circumstances Under Which Different Types of PS Would be Required

AdvaMed is aware that FDA's guidance document, "Guidance on Criteria and Approaches for Postmarket Surveillance" (Nov. 2, 1998), provides some examples of when various types of data collection might be appropriate. However, AdvaMed believes that more specificity is needed. Indeed, the costs of these different types of data collection vary significantly, and it is important that manufacturers have a clear understanding of the kind of expenses they may face if they choose to market a particular kind of device.

4. Additional Information is Required in Order to Arrive at an Accurate Estimate of the Costs of PS.

FDA estimates that "the total present value of the costs for primary data collection [will] be \$324,000 per PS study." 65 Fed. Reg. 52,383. As mentioned above, AdvaMed believes that FDA does not have authority to require primary data collection from clinical studies for PS; however, if FDA did in fact have the authority, AdvaMed believes the actual cost of primary data collection would be significantly higher than \$324,000. In order for AdvaMed to provide a more realistic estimate of the cost of primary data collection to refute FDA's cost estimates, it is necessary to understand in greater detail what "primary data collection" would entail. Thus, as stated above, AdvaMed respectfully requests that FDA provide more specificity regarding its expectations for PS studies. In addition, AdvaMed respectfully requests that FDA clarify how it arrived at the various cost estimates contained in the proposed rule. For example, the agency states that "[w]e have estimated that [normal physiologic] data would require a direct cost of \$150.00 per observation for the physician or medical facility to collect the data and submit it in proper form to the sponsoring manufacturer." 65 Fed. Reg. 52,382. AdvaMed respectfully asks that FDA explain how this figure was determined, e.g., how many facilities and manufacturers were surveyed in order to reach this estimate?

5. FDA Should Clarify Why Certain Categories of Devices are Likely to be Affected by the Proposed Rule.

In describing the impact of the proposed rule, FDA states:

Makers of four categories of devices are likely to be affected by the proposed regulations: Diagnostic substances (SIC 2835), surgical and medical instruments (SIC 3841), dental equipment and supplies (SIC 3843), and ophthalmic goods (SIC 3851).

65 Fed. Reg. 52,384. It is not clear to AdvaMed why these particular categories of devices

are likely to be affected by the proposed rule. Thus, AdvaMed respectfully requests that FDA provide clarification in this regard.

H. "Paperwork Reduction Act of 1995" Section, 65 Fed. Reg. 52,386

In this section, AdvaMed provides comments on several specific questions relating to the proposed rule's "collection of information" requirements.

1. Certain Aspects of the Proposed "Collection of Information" Are Not Necessary for the Proper Performance of FDA's Functions, and Would Generate Information Lacking in Practical Utility.

As part of its obligations under the Paperwork Reduction Act of 1995, FDA asks for comments on "[w]hether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility." 65 Fed. Reg. 52,386. AdvaMed sees at least two aspects of the proposed "collection of information" that are unnecessary and would generate information lacking in practical utility³:

- AdvaMed believes that it is unnecessary for manufacturers to obtain FDA approval for "any proposed modifications or changes in an ongoing study." See Proposed § 822.21. In AdvaMed's view, approval only should be required for significant changes.
- In AdvaMed's view, domestic manufacturers of devices for export only should not be subject to PS requirements. See 65 Fed. Reg. 52,379. The FDC Act's export provisions permit the export of, among other things, certain unapproved devices. Collection of PS data on such devices would be inconsistent with the objective of PS, which is to gather additional information on devices that already have been approved. In addition, conducting PS studies on devices for export only would not serve any United States public health interest, and, therefore, is a matter more appropriately addressed by the regulatory processes of the foreign countries importing these devices.

2. There Are Several Ways to Enhance the Quality, Utility, and Clarity of the Information Collected Pursuant to the PS Proposed Rule.

FDA also asks for comments "on ways to enhance the quality, utility, and clarity of the

³ Both of these points are discussed in detail above.

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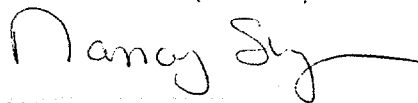
information to be collected." 65 Fed. Reg. 52,386. As discussed above, AdvaMed believes this could be accomplished in several ways:

- In AdvaMed's view, it is important that FDA be required to hold a meeting with the affected manufacturer(s) before a PS order is issued. Such a meeting would serve as a forum to discuss the nature of the PS question and what the agency expects to see in a PS plan. This process would enhance the quality of the PS plan ultimately submitted by the manufacturer(s).
- AdvaMed believes that PS plans submitted to the agency also would be of higher quality and greater utility if FDA provided more guidance as to what is expected in a PS plan, and the criteria that will be used in assessing PS plans.

* * *

AdvaMed appreciates the opportunity to provide comments on this proposed rule. Should you have any questions on the information presented in this document, please do not hesitate to contact us.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Nancy Singer", followed by a horizontal flourish line.

Nancy Singer
Special Counsel